Support Document #64

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D. C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 13, 2003

MEMORANDUM

SUBJECT: Policy Establishing Procedures for Reviewing and Approving New Science Policy

FROM: Steven Bradbury, Director
Environmental Fate and Effects Division (7507C)
Office of Pesticide Programs

TO: Environmental Fate and Effects Division

Effective immediately, the attached policy establishes the current procedures for the review and approval of new science policy develop by Technical Teams and special workgroups.

See *F:\User\Share\Policies, Guidance and Formats\Policies by Topic\Policy Approval Process* for an electronic copy of this document.

Attachment: The Environmental Fate and Effects Division's "Approval Process for Proposed Science Policy"

The Environmental Fate and Effects Division's
"Approval Process for Proposed Science Policy"

Steps for Science Policy Approval and Distribution (Technical Teams, Science Policy Panel (SPP), Quality Assurance (QA), Management Team, Administrative Team)

Science Policy is generally developed within one of EFED's six standing Technical Teams. However, on occasion proposed science policy may have elements that cross the disciplinary boundaries of a single Technical Team, thus requiring the cooperation of more than one team to propose and develop science policy. In addition, there are two formally established scientific workgroups that have responsibilities centered around major cross-discipline, scientific advancements. These groups, the Geographic Information Systems (GIS) Workgroup and the Refined Risk Assessment (RRA) Workgroup, will on occasion have the need to develop science policy for the Division.

When science policy is developed by more than one technical team or the GIS and RRA workgroups, the policy leader, or workgroup's designee, will be responsible for ensuring that the proposed science policy is discussed and reviewed in each of the appropriate technical teams who's contributions and areas of responsibilities will overlap the science ingrained in the policy. Each technical team involved in the review of science policy developed by another technical team or the GIS or RRA workgroup is expected to approve, approve with comment, or recommend approval with technical changes. Science policy comments or changes that result in differences of scientific opinion between the originating technical team, GIS or RRA workgroup will be captured in writing and appended to materials provided to the QA manager, Science Policy Panel, and management team during the science policy approval process.

The procedures that follow are designed to permit single and multiple Technical Teams and the GIS and RRA Workgroups to propose science policy for approval to EFED's management.

1) Science policy development. Science policy is developed under the umbrella of the appropriate Technical Team(s) (TT), the GIS Workgroup, and RRA Workgroup (henceforth, collectively referred to as Technical Teams) with an identified individual in the lead, Technical Team Policy Lead (TTPL), based on the Annual EFED Project Plan. On occasion, more than one technical team may sponsor a policy[1]. The GIS and RRA workgroups, when sponsoring science policy, will request appropriate technical team(s) review and comment. The proposed science policy is discussed by the TT(s) and approved. Comments provided by technical teams,

[1] When science policy development involves expertise from more than one technical team, a single TTPL is recommended.

including comments from technical teams other than the sponsor, will be captured and appended to the science policy provided for subsequent reviews. The TTPL is responsible for posting the announcement of the proposed science policy to the Policy Development Status Report, maintained on F:\\User\Share\Tech Teams, Policy Panel and Risk Review Panel\Policy Tracking Table and periodically updating that report as it proceeds through each step of the review and approval process. The TTPL sends the proposed science policy to the Division's Quality Assurance (QA) manager and SPP for concurrent review. **[TTPL updates the Status Report to reflect this date]**

2) Concurrent review by the QA manager and the SPP. The QA review is responsible for ensuring that the data sources are properly described and documented. These sources include meta data, data quality and data uncertainty. The QA lead will return comments to the TTPL to revise science policy accordingly. The SPP is responsible for reviewing science policy to ensure that it is consistent with good scientific practices and principles and with broad Agency policy governing the same topic. **[TTPL updates the Status Report to reflect this date]**

2a) The SPP schedules review of the proposed science policy and informs the TTPL and TT chairs of the SPP discussion date. This meeting is set as soon as possible following receipt of the proposed science policy. The chair of the SPP updates the Science Policy Development Status Report to indicate the date the proposed science policy will be discussed. The SPP reviews the proposed science policy and sends comments to the TTPL and TT chairs. The SPP must indicate whether the comments are minor* or major* (defined below), and updates the Science Policy Development Status Report to indicate the proposed science policy has been discussed and comments sent to the TTPL and TT chairs. If comments are minor and after revisions can be forwarded to management for review without the SPP's further input, a note affirming this to the TTPL and appropriate TT chairs must accompany the comments with a cover memo and all background documents[2]. The QA manager or his/her designee and the SPP will have a maximum of 4 weeks for review and comment.

3a) Response to Minor SPP Comments

If comments are minor* and the SPP included a note affirming that further review by the SPP is not necessary following revision or if no changes are recommended, the TTPL and TT chairs will make sure comments are addressed and will route the proposed science policy, cover memo[3], and all background documents (via email) to the management team for discussion and

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[2]Background documents include: TT science policy development comments, QA comments, SPP comments, TT(s) and SPP response to comments, TT(s) management representative note.

[3]Cover memo must follow the format provided and include the location on the F-Drive where the science policy will be stored and the effective date of the science policy.

approval. The TTPL/TT(s) revisions and submission to management occur within a maximum of 4 weeks of receipt of QA and SPP comments. **[TTPL updates the Status Report to reflect this date]** Proceed to step 4.

3b) Response to Minor Comments Needing Further SPP Review

The SPP may request a second review after addressing minor comments before submitting the proposed science policy to management. The TTPL will evaluate the comments and present the SPP's comments and draft response to comments at a TT meeting.

If the TT concurs on how to address the SPP's comments, revisions are made and the proposed science policy is routed back to the SPP for review. TTPL/TT(s) revisions occur within a maximum of 4 weeks of receipt of SPP initial comments. If SPP is satisfied with the revisions or has additional minor* comments, the SPP routes the science policy back to the TTPL within a maximum of 2 weeks of receipt of TTPL/TT(s) revisions and provides a note affirming no further SPP review is required. The TTPL/TT(s) will route the proposed science policy (via e-mail) to the management team for discussion (Step 4) within a maximum of 3 weeks. If the TTPL/TT(s) does not agree with the SPP's additional comments, the TTPL/TT(s) forwards the proposed science policy package to the management team, includes its response to comments in the cover memo and copies the chair of the SPP. Disagreements of this nature constitute a major* comment and will follow the procedures in 3c.

3c) Response to Major SPP Comments[4]

If comments are major* the TTPL will evaluate the comments and present the SPP's comments and draft response to comments at a TT meeting. Following TT discussions, the TTPL will revise the response to comments and schedule a discussion at the Chemical Review Process meeting (CRP) within a maximum of 4 weeks of receipt of the SPP's comments. **[TTPL updates the Status Report to reflect this date]** The TTPL will provide the SPP's comments and their response to comments document to the Management team no less than two weeks in advance of the CRP meeting. In addition, the TTPL forwards the response to comments to the SPP Chair for their review. The SPP's evaluation of the response to comments will be made available to the TTPL/TT chairs and management team no less than 2 weeks in advance of the CRP meeting date. The discussion at the CRP meeting occurs within a maximum of 6 weeks of the TT receipt of the SPP initial comments.

The CRP discussion will be lead by the TTPL and will include a discussion of the response to the SPP comments and an estimate of additional time to address the comments and

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[4]Major comments also apply to minor comments which cannot be resolved by the Technical Teams and the SPP. When any SPP comment is classified as "major," this process is followed even if minor comments are also included.

revise the proposed science policy. Discussions at the CRP meeting will be captured b designated CRP scribe and provided to attendees one week following the CRP meeting. Management will decide if they concur that major* revisions are needed. If major* revisio needed, management will indicate if resources are available, and set a schedule for completi the science policy. The TTPL/TT(s) will provide management a proposed plan for science pol revisions no more than 4 weeks following the CRP meeting. In this case, the science policy approval process described above in steps 1-3 is repeated. If the management team decides that the proposed science policy can go forward with minor revisions, the rationale for the decision will be documented by the management representative to the tech team in a written response to the TTPL, the TT(s), SPP, and management team one week following the CRP meeting. The TTPL/TT(s) will revise the proposed science policy within 2 weeks and submit to management for review, the process described in step 4. If the management team decides resources are not available to support continued revisions to the proposed science policy, all work will be stopped until the next annual budget process.

4) The management team reviews the proposed science policy, cover memo and all accompanying background documents and makes a recommendation to the Division Director (DD) regarding approval within 3 weeks of receipt of the proposed science policy. Management's comments on the proposed science policy are provided to the TTPL within no more than one week of the management discussion.

5) The management representative works with the TTPL to make editorial revisions. The revised proposed science policy and cover memo are forwarded to the DD for approval by the management representative or TTPL via e-mail and a hard copy is routed to the DD for signature within a maximum of 2 weeks of receipt of the management teams comments. The DD comments on science policy and submits them to TTPL/TT within one week of receipt of proposed science policy. The TTPL/TT revises the science policy and cover memo and returns to DD for signature within one week of receipt of DD's comments. The DD signs the science policy (hand/electronically) within one week of receipt of revised science policy.

6) The administrative team distributes the science policy to all electronically. The administrative team posts the final science policy in the location designated by the TT on the F: drive. A signed hardcopy is retained in the front office file. These activities occur within one week of science policy receipt.

Interim and Emergency Science Policy Approval

On occasion, interim or emergency science policy may need developing, expedited review and approval. Although difficult to capture all conditions where this will be necessary, emerging exposure, hazard or risk assessment methodologies where none exist and where the program may be at substantial risk if it cannot address uncertainties are several. Other interim or emergency science policy includes those that correct an error or omission for a practicing

methodology or procedure. Proposed science policy, whether proposed as interim c requiring expedited implementation will be discussed at a CRP meeting. The TT co-c TTPL will be responsible for scheduling the discussion at a CRP meeting. The CRP me where the proposed science policy will be discussed must include the majority of the management team, the SPP chair (or his/her designee) and a division QA manager. One wee advance of the CRP meeting, the TT co-chairs or TTPL must provide documentation to the management team for discussion. Documentation should identify the issue requiring expedited science policy review, what primary uncertainty, error, or omission the policy is addressing and an approximate time line, including resources, for placing the proposed science policy into expedited review. The chair of the SPP and QA manger are present as a means to alert them of the need for expedited review and to provide input on the time line.

At the CRP meeting, the management team will determine if the proposed science polic meets the conditions for expedited review and approval. If approved for expedited review, the policy approval process described above will be followed. However, the QA manager, SPP, and management will place emphasis on expediting review given the nature of the issue.

**Minor: typographical errors, format errors, marginal editorial comments, questions which ar easily addressed without further research, comments which can be addressed by clarifying the grammar or language in the science policy.*

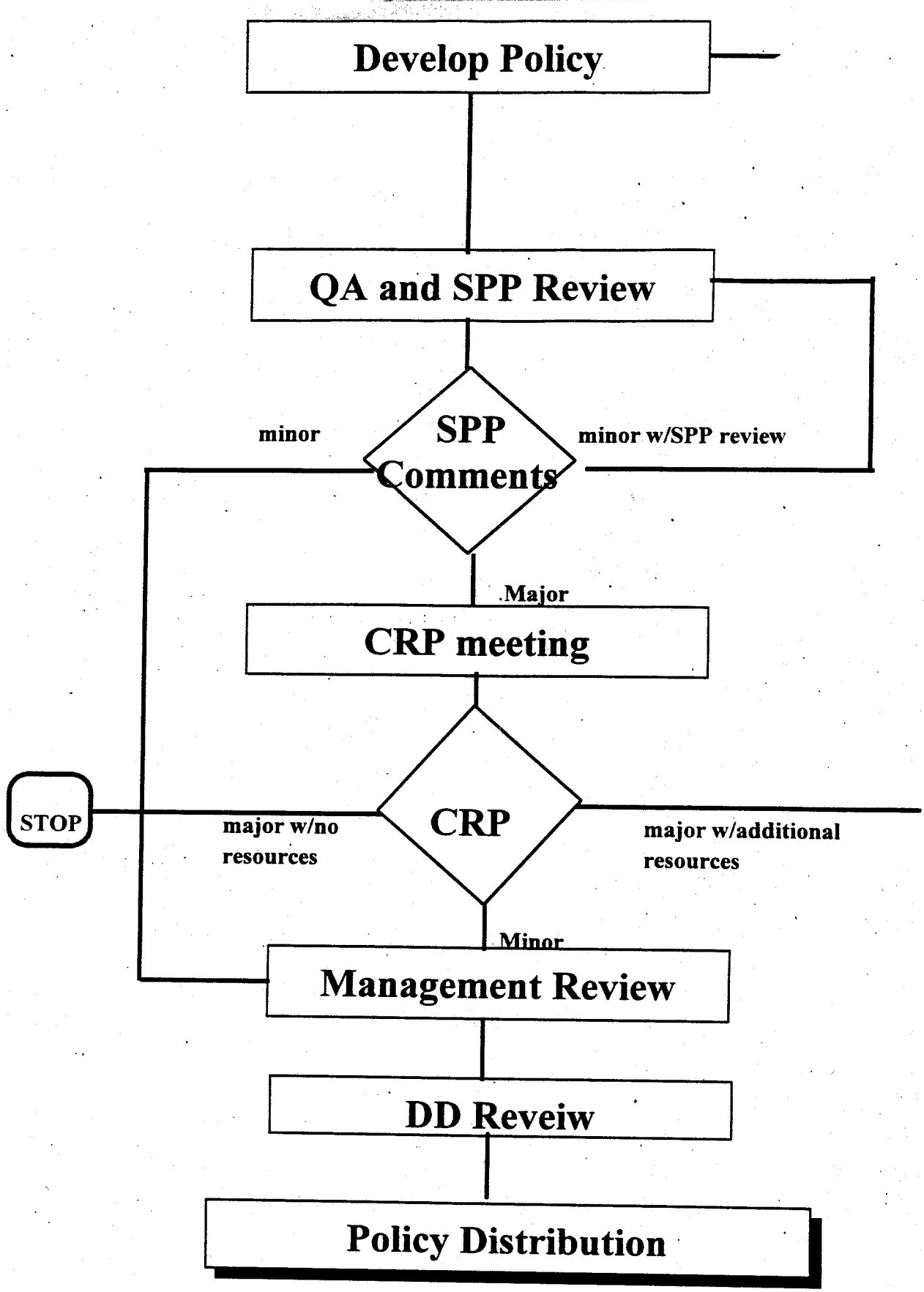
**Major: restructuring or major reorganization of the document required, SPP disagrees overall with the science policy proposed on technical or risk management grounds, SPP questions are open-ended and require significant work or research to address.*

Milestone	Deliverable	timeframe	who develops or delivers it	where it goes next
1. Proposed new Policy is approved by the Technical Team (or other designated entity).	Proposed Policy document	Within the fiscal year	TTPL	The Division Quality Assurance (QA) manager or his/her designee.
2. QA and SPP Review QA manager or designee provides QA comments. TT revises document	QA comment document	Maximum 4 weeks for review and comment from delivery by TTPL	The Division Quality Assurance (QA) manager or his/her designee	TTPL and TT Co-chairs
The SPP schedules review of the proposed policy and discusses proposed policy	Set date of SPP discussion SPP comment document Memo indicating if comments are minor, minor needing further SPP review, or major		SPP chair	
3A. TT response to minor SPP comments and submission to Management Team	Revised proposed policy document and background documents (QA comments, TT response to QA comments, SPP comments, SPP memo, TT response to SPP comments)	within 4 weeks of receipt of SPP comments.	TTPL and TT Chairs	the management team
3B. TT Response to Minor Comments Needing Further SPP Review	Revised proposed policy. Response to comments document	TTPL/TT(s) revisions occur within 4 weeks of receipt of SPP initial comments.	TTPL and TT Chairs	SPP chair

Milestone	Deliverable	timeframe	who develops or delivers it	where it goes next
Second Round SPP review SPP determines if revisions or response to comments is adequate. Routes proposed policy to TTPL with a memo summarizing SPP position.	SPP memo indicating comments have been addressed and no SPP review needed or SPP memo indicating comments have not been adequately addressed.	within 2 weeks of reciept of TTPL/TT(s) revisions	SPP chair	TTPL/TT co-chairs
TT response to second SPP review and submission to the Management team The TPTL revises policy as determined by TT and develops a comment response document.	Revised proposed policy document and background documents (QA comments, TT response to QA comments, SPP comments, SPP memo, TT response to SPP comments)	within 3 weeks of receipt of SPP comments.	TTPL and TT Chairs	the management team
3C. TT Response to major SPP comments TTPL evaluates comments and presents the SPP's comments and a draft response-to-comments at a TT meeting. Following TT discussions, the TTPL will revise the response to comments and schedule CRP meeting	Response to SPP comments. Revised proposed policy document after TT discussion	within 4 weeks of the TT receipt of the SPP comments.	TPTL	TT
	schedule CRP meeting	CRP meeting scheduled to occur within 6 weeks of the TT receipt of the SPP comments.	TTPL/TT	CRP meeting attendees (includes: TT co-chairs, TTPL SPP chair Mana T

Milestone	Deliverable	timeframe	who develops or delivers it	where it goes next
CRP meeting preparation The TTPL schedules a discussion (see Rachelle) at the Chemical Review Process Meeting (CRP) meeting. TTPL and SPP co-chair make all background documents available to meeting attendees.	Revised proposed policy, Background documents (SPP comments, TT response to SPP comments, etc.) TT estimate of time and resources needed to complete policy development	all documents to CRP attendees 2 weeks in advance of the CRP meeting	TTPL, SPP chair (if response document is developed)	CRP meeting attendees
CRP meeting	characterization of comments (major/minor)	at the CRP meeting	management team	TTPL/TT
	If major revisions are needed, management decision on resource availability and policy development schedule	at the CRP meeting	management team	TTPL/TT
	CRP meeting summary	1 week	designated CRP scribe	CRP meeting attendees
	If minor revisions needed, management decision memo	1 week	management representative	CRP meeting attendees
TT Follow up to CRP meeting. Tech Team discusses CRP outcomes	If major* revisions are needed, discussion in TT regarding CRP decision and followup plans	maximum 4 weeks to refine plan for policy development.	TTPL/ TT co-chairs	management team
	If minor revisions needed, revised policy and submit to management team	maximum 2 weeks to make minor revisions and submit revised policy	TTPL/ TT co-chairs	management team

Milestone	Deliverable	timeframe	who develops or delivers it	where it goes next
4. Management Team Policy Review Management team discusses policy and works with TT to revise and submit to DD for review/approval	Recommendation to DD on policy approval	within 3 weeks of receipt of the proposed policy.	management team	DD
	Comments on proposed policy document	within 1 week of management discussion	management representative	TTPL
5. DD policy Review/ Approval	Revised proposed policy document and cover memo (email and hardcopy)	within 2 weeks of receipt of the management teams comments.	TTPL/TT	DD
	comments on policy and cover memo	within 1 week	DD	management representative/TT
	revised policy and cover memo	within 1 week of receipt of comments	TTPL/TT	DD
	signed policy (hand/electronically)	within 1 week of receipt of revised policy	DD	admin team
6. Policy Distribution and Storage	Signed policy (e-copy)	within 1 week of receipt of signed policy	admin team	EFED staff
	Signed policy (e-copy and hardcopy)	within 1 week of receipt of signed policy	admin team	electronic and hardcopy storage as designated by TTand front office file



FLOWCHART FOR POLICY APPROVAL PROCESS

EPA United States Environmental Protection Agency

Office of Pesticide Programs

ORGANIZATIONAL STATEMENT FOR EXPOSURE MODELING WORK GROUP

(8/2/2002) Support Document #66

Overall Vision

The Exposure Modeling Work Group (EMWG) will discuss technical model related pesticide exposure issues in the context of FIFRA and FQPA.

Mission Statement

The mission of the EMWG is to:

- Improve the quality of the science of estimating environmental exposure and provide timely support to address technical needs as defined on an annual basis by the Environmental Fate and Effects Division (EFED) of the EPA Office of Pesticide Programs (OPP).
- Provide a forum for cooperative exchange of facts and technical information on technical issues related to pesticide exposure modeling between EFED and key stakeholders with similar technical expertise.
- Center on aquatic exposure issues in the near to mid-term.

NOTE - *EMWG will not discuss issues of EPA policy. Should such issues arise, they will be identified by the EFED management representative and forwarded to appropriate groups for resolution.*

EMWG Organization

The EMWG is chaired by EFED (Designated co-chair of the Water Quality Tech Team). The chair will be responsible for posting Federal Register notices, and for organizing the meeting. Stakeholder input will be sought on the agenda, which will focus on technical areas that EFED would like the EMWG participants to address. The final meeting agenda will be approved by the meeting chair and should reflect relevant stakeholder input. An EFED management representative (Branch Chief level or above, or an alternate designated by the Director of EFED) will attend all EMWG meetings to ensure that policy issues are not discussed in meeting discussions. Should such issues arise, they will be forwarded to appropriate groups for resolution.

EMWG Meeting Administration

- The EMWG will meet approximately quarterly, or at the call of the meeting Chair.
- All meetings will be public with announcements of date, time, and venue made by OPP/EFED in advance (at least 30 days) in the Federal Register.
- The Federal Register notice will include a draft meeting agenda developed by OPP/EFED. Comments will be solicited on the meeting agenda, and the final agenda will reflect relevant public input.
- Space will be adequate to accommodate a reasonable number of people (up to 60 participants). The Federal Register notice will provide information regarding how to register

for the meeting, and if special accommodation is needed.

- EPA will provide a list server communications structure to share the agenda, minutes, and relevant background documents and to facilitate participation in the meeting.
- Minutes will be written for all EMWG meetings and made publicly available via the OPP web site.
- This workgroup will be examined annually and will exist until the EFED Division director determines it is no longer needed. This charter will be in effect for two years from the date it is developed, and may be renewed or revised as needed.

Membership

All meetings will be announced in advance in the Federal Register and will be open to the public. It is anticipated that core participants will be scientists with balanced representation from stakeholders, including:

EFED-OPP/EPA	NERL/EPA	NRMRL/EPA
Office of Water/EPA	OSWER/EPA	Industry
US Geologic Survey/DOI	ARS/USDA	
NRCS/USDA	NGOS	AWWA
SFIREG	Academics	Consultants

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www.epa.gov/oppefed1/models/water/emwg_org_statement.htm
updated August 2, 2002